March 27, 2017

Mr. Timothy Lockwood
Chief, Regulation and Policy Management Branch
California Department of Corrections and Rehabilitation
P.O. Box 94283-0001
1515 S Street
Sacramento, CA 95811

Re: Comments Regarding Proposed Lethal Injection Regulations
CDCR's Notice of Change to Text as Originally Proposed

Dear Mr. Lockwood,

The American Civil Liberties Union of California continues to have grave concerns about the California Department of Corrections and Rehabilitation's ("CDCR" or "the Department") proposed lethal injection regulations.[1] The revisions do not address the defects raised by the Office of Administrative Law's December 28, 2016 Decision of Disapproval and only introduce additional areas of noncompliance with the Administrative Procedure Act. In addition, the flaws in the proposed regulations remain fundamental and cannot be remedied by amendments that tinker around the edges. CDCR should therefore decline to proceed with the proposed action. *See* Gov't Code § 11347. Instead, it should recommence its process for developing proposed lethal injection regulations and address in a meaningful fashion the fundamental flaws in its proposed protocol identified in these comments and the ACLU's previously submitted comments.

CDCR's changes in the text as originally proposed raise the following concerns:

1. Section 3349(a) through 3349(d). Failure to follow APA procedures regarding incorporation of forms by reference.

The changes to the proposed text of 3349(a) through 3349(d) involve incorporation by reference of Forms 1801, 1801-A and 1801-B. But the Final Statement of Reasons does not contain the necessary demonstrations to incorporate documents by reference. *See* CCR, title 1, § 20(c). The Department's statement of reasons should be amended to address this defect.

2. Section 3349.1(n). Clarity.

[1] The American Civil Liberties Union of California consists of the American Civil Liberties Union of Northern California, the American Civil Liberties Union of San Diego and Imperial Counties, and the American Civil Liberties Union of Southern California.

ACLU OF NORTHERN CALIFORNIA
Abdi Soltani, Executive Director
39 Drumm Street
San Francisco, CA 94111
(415) 621-2493

ACLU OF SOUTHERN CALIFORNIA
Hector Villagra, Executive Director
1313 West Eighth Street
Los Angeles, CA 90017
(213) 977-9500

ACLU OF SAN DIEGO & IMPERIAL COUNTIES
Norma Chavez-Peterson, Executive Director
P.O. Box 87131
San Diego, CA 92138
(619) 232-2121

The change to Section 3349.1(n) is the addition of the term "Ministers of the Gospel," which is defined as "a person serving as an agent specific to a system of beliefs." The meaning of the term "an agent specific to a system of beliefs" is entirely unclear.

First, Merriam-Webster defines an "agent" as "one that acts or exerts power" or "something that produces or is capable of producing an effect." *See* Merriam-Webster, available at https://www.merriam-webster.com/dictionary/agent. It is not clear what it means for someone to act or exert power specific to a system of beliefs. It is also not clear what it means for something to produce or be capable of producing an effect specific to a system of beliefs. Assuming "agent" is used in a legal sense, the ambiguity issues are not ameliorated. The text should be amended to provide an intelligible definition of the term "Ministers of the Gospel."

Second, the term is "Ministers of the Gospel." The Gospel refers to a specific set of Christian teachings. But the definition in the proposed regulation is not limited to Christian teachings and instead refers more generically to "beliefs." This inconsistency creates a fatal ambiguity.

Third, the term "system of beliefs" is so vague that it could refer to anything ranging from belief in a particular religion, to belief in extraterrestrial life, or belief that certain diets promote good health.

The definition should be amended to address this lack of clarity.

3. Form 1801C. Clarity.

This form has been changed to replace the term "Spiritual Advisors" with "Ministers of the Gospel." The term "Ministers of the Gospel" is unclear for the reasons stated above. The form should be amended to address this defect.

4. Form 1801C. Consistency.

This form has been changed to replace the term "Spiritual Advisors" with "Ministers of the Gospel." An average person would understand the term "Ministers of the Gospel" to mean a minister affiliated with the Christian faith. But by singling out advisors associated with a particular religion, this provision favors one religion over another and favors religion over non-religion. This violates the federal Establishment Clause and parallel provision of California's Constitution. *See, e.g., Epperson v. Arkansas*, 393 U.S. 97, 104 (1968) (Establishment Clause of "First Amendment mandates government neutrality between religion and religion, between religion and nonreligion"); *Everson v. Bd. of Educ.*, 330 U.S. 1, 18 (1947) (Establishment Clause of First Amendment "requires the state to be a neutral in its relations with groups of religious believers and non-believers"); *East Bay Asian Local Dev. Corp. v. Cal.*, 24 Cal. 4th 693, 718 (2000) (construing California Constitution's article 1, section 4's prohibition against laws "respecting an establishment of religion" in light of federal Establishment Clause); *Fox v. City of Los Angeles*, 22 Cal. 3d 792, 796 (1978) (in addition to prohibiting establishment of religion, "[t]he California Constitution also guarantees that religion shall be freely exercised and enjoyed

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P.O. Box 87131
San Diego, CA 92138
(619) 232-2121

'without discrimination or preference.' Preference thus is forbidden even when there is no discrimination."). This conflict with the federal and state constitutions raises a consistency issue. The form should be amended to remedy this defect.

5. Section 3349.4(e). Clarity.

The change to Section 3349.4(e) is to add the bolded language: "The Team Supervisor shall conduct and document monthly security and operational inspections of the Lethal Injection Facility, **to include the following**:". The proposed text then specifies several items, such as "Supply inventory." The new language is unclear in two respects.

First, "to *include* the following" suggests that the items that follow are a non-exclusive list. But if additional items are to be included in the inspections, it is unclear what they are.

Second, "to include the following" immediately follows the term and therefore grammatically modifies "the Lethal Injection Facility" rather than "inspections." It is unclear how, for example, "Functionality of equipment" could be included in the Lethal Injection Facility.

The language should be amended to address this lack of clarity.

6. Section 3349.4(e)(4). Failure to follow APA procedures regarding incorporation of forms by reference.

The new text proposes to incorporate by reference Form 2137. But the Final Statement of Reasons does not contain the necessary demonstrations to incorporate documents by reference. *See* CCR, title 1, § 20(c). The Department's statement of reasons should be amended to address this defect.

7. Form 2137. Clarity.

Form 2137 contain numerous terms, the meaning of which are not provided and unclear. These include "Fire Ext."; "OC (MK-4)"; and "PPE."

In addition, it is unclear what the inspection is supposed to check for. For example, under "Building Maintenance," there is an item for "Refrigerator (Temp.)." This presumably means that the inspection should check the refrigerator's temperature, but neither the regulatory text nor the form specify what temperate is considered appropriate.

The form should be amended to address this lack of clarity.

8. Form 2137. Recommendation.

Form 2137 contains three main sections, pertaining to "Building Maintenance," "Equipment," and "Supplies." The form indicates that the inspection should note whether the specific items listed under "Building Maintenance" are "Clean" or instead in "Need[] [of] Cleaning." But the form does not note whether the specific items listed under "Equipment" or "Supplies" are or are not clean. This is particularly troubling because the "Supplies" include "I.V. Supplies" and "Infusion Supplies," which should be inspected not only for cleanliness but for sterility. This is especially troubling because, as noted in the ACLU's prior comments, CDCR's own documents demonstrate that the Lethal Injection Facility suffers from "overall cleanliness" problems. (*See* Exhibit 1, excerpts of documents produced by CDCR in response to September 4, 2015 ACLU Public Records Act request).

The form should be amended to specify that "Equipment" should be inspected for cleanliness and "Supplies" should be inspected to ensure sterility.

9. Section 3349.5(f)(5). Clarity and necessity.

The change to this section involves the addition of the bolded language:

(f) The San Quentin Warden shall:…
(5) Ensure the Team Administrator, the Team Supervisor and all Lethal Injection Team members involved in the lethal injection process understand their roles in the scheduled execution, **by reviewing the following:**
(A) Training session performance assessments.
(B) Most recent staff performance in job duties to include annual personnel evaluation and any corrective or adverse action.
(C) Any other information or concerns expressed by the Team Administrator, Team Supervisor or Lethal Injection Team Member.
(D) Any other information that cases the San Quentin Warden to believe persons identified in subsection (5) may be unprepared or unable to perform the duties during a scheduled execution.

First, the new language creates a conflict with the Initial Statement of Reasons ("ISR"), which provides that the "San Quentin Warden *may* consider the training session performance assessments…" and other specified information. (ISR at 26 [emphasis added].) The text, however, uses the mandatory "shall." This conflict between the regulatory text and ISR, as to whether the Warden must or only may consider the specified information, creates a clarity issue.

Second, one of the items to be reviewed is "Training session performance assessments," but nowhere do the text of the regulations state that training session performance is to be assessed, and if so, how and by whom the Team Administrator, Team Supervisor and Team Members would be assessed. This ambiguity creates a clarity issue.

Third, one of the items to be reviewed is "Most recent staff performance in job duties to include annual personnel evaluation and any corrective or adverse action." The ISR however refers to "recent performance in job duties, to include personnel evaluations or corrective and

adverse action taken against the specific Lethal Injection Team member." (ISR at 26.) Whereas the text of the regulation calls for review of "annual personnel and *any* corrective or adverse action," the ISR only refers to "*recent* performance…, to include personnel evaluations or corrective and adverse action…." (Emphasis added.) The text of the regulation and ISR are thus inconsistent as to whether *any* corrective or adverse actions, regardless of date, or only *recent* corrective or adverse actions are to be considered. This conflict creates a clarity issue.

Fourth, Section 3349.5(f)(5)(C) states that the San Quentin Warden shall review "Any other information or concerns expressed by the Team Administrator, Team Supervisor or Lethal Injection Team Member." The ISR, by contrast, refers more narrowly to "any concerns expressed by the Team Administrator, Team Supervisor or Lethal Injection Team Member," but contains no reference to "Any other information." This conflict between the text and the ISR create a clarity issue. Also, there is no limitation or modification of the term "Any other information." Is the San Quentin Warden truly required to review *any* information expressed by these individuals, including information that has no bearing on their understanding of their roles in the scheduled execution? The broad term "Any other information" also creates a clarity issue.

Fifth, Section 3349.5(f)(5)(C) states that the San Quentin Warden is to review "Any other information…expressed by the Team Administrator, Team Supervisor or Lethal Injection Team Member." But the purpose of this review is to "[e]nsure" that these individuals "understand their roles in the scheduled execution." The ISR does not explain why it is necessary for the Warden to review *any information*, even information wholly unrelated to the scheduled execution, to further this purpose. The Department's explanation does not demonstrate by substantial evidence the need for the regulation's requirement for the Warden to review "[a]ny other information," and therefore, does not satisfy the necessity standard.

Sixth, Section 3349.5(f)(D) states that the Warden shall review "Any other information that causes the San Quentin Warden to believe persons identified in subsection (5) may be unprepared or unable to perform the duties during a scheduled execution." But this language provides no description of how the Warden is to assess whether information should cause him or her to believe that someone is unprepared or unable to perform duties. There is no description on the type of information that would support such a belief. This ambiguity creates a clarity issue.

Seventh, Section 3349.5(f)(D) states that the Warden shall review "Any other information that causes the San Quentin Warden to believe persons identified in subsection (5) may be unprepared or unable to perform the duties during a scheduled execution." But the purpose of this review is to "[e]nsure" that these individuals "understand their roles in the scheduled execution." The ISR does not explain why it is necessary for the Warden to review information related to preparedness or ability to perform duties during a scheduled execution in order to ensure that individual understands his or her role in the execution. One can be unable to perform duties (for example, because of a cold), but fully understand those duties. The ISR thus fails to explain why it is necessary to review information related to *preparedness or ability to perform* duties, to further the purpose of ensuring individuals *understand* their duties. The Department's explanation does not demonstrate by substantial evidence the need for the regulation, and therefore, does not satisfy the necessity standard.

The regulation and the Department's statement of reasons should be amended to address these defects.

10. Section 3349.6(a)(4). Clarity.

The changes to the text are as follows: "If the San Quentin Warden ~~and~~ **or** the Warden at the institution where the inmate is house ~~have~~ **has** good reason to believe the inmate has become insane after reviewing **any of** the **three** 20-Day Pre-Execution Reports, the San Quentin Warden shall notify the District Attorney pursuant to Penal Code Section 3701."

The new text still fails to set forth clear parameters for determining what constitutes "good reason to believe the inmate has become insane." In a response to a comment, the Department stated: "A single opinion questioning the inmate's sanity is sufficient to trigger the statutory requirements mandating that the warden must call such fact to the attention of the District Attorney." (Final Statement of Reasons ("FSR"), Exh. G pp. 897-898 (Response to Comment 30403(38).) The new text simply provides that the San Quentin Warden or the Warden of the institution where the inmate is housed may formulate a belief as to the inmate's insanity after reviewing one or more of the 20-Day Pre-Execution Reports. But it does not provide any guidance to the Wardens about how to evaluate those Reports. In other words, the text of the regulation merely instructs the Wardens what information they must review (one or more of the Reports); but it does not provide guidance about the weight or significance the Wardens are to assign to those Reports. The response to the comment in the FSR by contrast sets a very clear standard – if any one opinion questions the inmate sanity, that must be relayed to the District Attorney. This expansion of the meaning of the regulation text creates a conflict between the language of the regulation and the Department's description of the effect of the regulation in violation of clarity standard. The regulation should be amended to address this defect.

11. Section 3349.6(b). Clarity.

This provision specifies when the alienists are to conduct their second interviews and evaluations of the inmate. The change to the text is as follows: "~~Approximately~~ **No sooner than** ten calendar days prior to the scheduled execution." The Office of Administrative Law ("OAL") previously found that the term "Approximately" lacked clarity. But the phrase "No sooner than" raises the identical concerns previously articulated by OAL. "No sooner than" still "creates an unspecified amount of leeway in interpreting the regulation and members of the directly affected public could reasonably interpret this time frame to mean different things….Would an alienist's 7-Day Pre-Execution Report be in compliance with subdivision (b) if it was prepared eleven days before the execution? Would twelve days be compliant?" (OAL Decision of Disapproval at 6.) Further, the highly malleable term "No sooner than ten calendar days" is inconsistent with the Department's statement that "ten days is *necessary* to allow the alienists approximately three calendar days to complete the duties required by the second evaluation of the inmate's sanity…" (ISR at 30.) This ambiguity and this conflict create a clarity issue. The regulation should be amended to address this defect.

12. Section 3349.6(g)(1). Clarity and necessity.

The change to this section involves addition of the bolded language:

(g)(1) The San Quentin Warden shall confirm that all Lethal Injection Team members are fully prepared and ready to perform their assigned duties by reviewing the following:
(A) Training session performance assessments.
(B) Most recent staff performance in job duties to include annual personnel evaluation and any corrective or adverse action.
(C) Any other information or concerns expressed by the Team Administrator, Team Supervisor or Lethal Injection Team Member.
(D) Any other information that cases the San Quentin Warden to believe any team member may be unprepared or unable to perform the duties during a scheduled execution.

First, the new language creates a conflict with the Initial Statement of Reasons ("ISR"), which provides that the "San Quentin Warden *may* consider performance during training sessions, any concerns expressed by the Intravenous Sub-Team leader, Infusion Sub-Team leader, Team Administrator, Team Supervisor, or any Lethal Injection Team member; recent performance in job duties, to include personnel evaluations or corrective and adverse action taken against the specific Lethal Injection Team member; and any other information that causes the San Quentin Warden to believe that the specific Lethal Injection Team member may be unprepared or unable to perform the duties required by these regulations during a scheduled execution." (ISR at 34 [emphasis added].) The text, however, uses the mandatory "shall." This conflict between the regulatory text and ISR, as to whether the Warden must or only may consider the specified information, creates a clarity issue.

Second, one of the items to be reviewed is "Training session performance assessments," but nowhere do the text of the regulations state that training session performance is to be assessed, and if so, how and by whom Lethal Injection Team members would be assessed. This ambiguity creates a clarity issue.

Third, one of the items to be reviewed is "Most recent staff performance in job duties to include annual personnel evaluation and any corrective or adverse action." The ISR however refers to "recent performance in job duties, to include personnel evaluations or corrective and adverse action taken against the specific Lethal Injection Team member." (ISR at 26.) Whereas the text of the regulation calls for review of "annual personnel and *any* corrective or adverse action," the ISR only refers to "*recent* performance…, to include personnel evaluations or corrective and adverse action…." (Emphasis added.) The text of the regulation and ISR are thus inconsistent as to whether *any* corrective or adverse actions, regardless of date, or only *recent* corrective or adverse actions are to be considered. This conflict creates a clarity issue.

Fourth, Section 3349.6(g)(1)(C) states that the San Quentin Warden shall review "Any other information or concerns expressed by the Team Administrator, Team Supervisor or Lethal

Injection Team Member." The ISR, by contrast, refers more narrowly to "any concerns expressed by the Team Administrator, Team Supervisor or Lethal Injection Team Member," and excludes the reference to "Any other information." This conflict between the text and the ISR create a clarity issue. Also, there is no limitation or modification of the term "Any other information." Is the San Quentin Warden truly required to review *any* information expressed by these individuals, including information that has no bearing on whether they are fully prepared and ready to perform their assigned duties? The broad term "Any other information" also creates a clarity issue.

Fifth, Section 3349.6(g)(1)(C) states that the San Quentin Warden is to review "Any other information…expressed by the Team Administrator, Team Supervisor or Lethal Injection Team Member." But the purpose of this review is to "[e]nsure" that these individuals "understand their roles in the scheduled execution." The ISR does not explain why it is necessary for the Warden to review *any information*, even information wholly unrelated to the scheduled execution, to further this purpose. And indeed, the ISR only references review of "concerns expressed by the Team Administrator, Team Supervisor or Lethal Injection Team Member" (ISR at 34), not the broader universe of "Any other information and concerns expressed by" these individuals. The Department's explanation does not demonstrate by substantial evidence the need for the regulation's requirement to review *any* information, and therefore, does not satisfy the necessity standard.

Sixth, Section 3349.6(g)(1)(D) states that the Warden shall review "Any other information that causes the San Quentin Warden to believe any team member may be unprepared or unable to perform the duties during a scheduled execution." But this language provides no description of how the Warden is to assess whether information should cause him or her to believe that someone is unprepared or unable to perform duties. There is no description on the type of information that would support such a belief. This ambiguity creates a clarity issue.

The regulation and Department's statement of reasons should be amended to address these defects.

13. Section 3349.6(i)(2)(B) and Form 2181. Clarity.

Section 3349.6(i)(2)(B) states: "A sedative is available upon request. If requested by the inmate, the sedative shall be administered under the direction and approval of a physician." Form 2181 has been amended as follows: "Inform the inmate that a sedative is available~~. Valium or its equivalent will be administered~~ under the direction and approval of a physician."

The text states in no uncertain terms that a sedative is available upon request. But the form states that a sedative is only available if a physician approves it. Further, the Addendum to the ISR indicates that an inmate who requests a sedative will only receive one if it is approved by a physician. (Addendum to ISR at 1 ["If any inmate requests a sedative at any time, the request will be evaluated by a physician and, *if approved*, a sedative shall be administered under the physician's direction."] [emphasis added].) The ISR thus significantly narrows the language of the regulation, which otherwise sets forth the unqualified right of an inmate to receive a sedative

"upon request." This conflict between the text of the regulation, the form, and the Addendum to the ISR create a clarity issue. The regulation should be amended to address this defect.

14. Form 2181. Failure to follow APA procedures regarding incorporation of forms by reference.

Section 3349.6(i)(1)(B) incorporates Form 2181 by reference. But the Final Statement of Reasons does not contain the necessary demonstrations to incorporate documents by reference. *See* CCR, title 1, § 20(c). The Final Statement of Reasons should be amended to address this defect.

15. Section 3349.6(i)(2) through 3349.6(i)(2)(B) & Addendum to Initial Statement of Reasons. Necessity.

The underlying regulatory provision states that the inmate is to be informed three hours prior to the execution about the availability of a sedative. The OAL previously found that CDCR had provided "no rationale … for why a sedative is being made available to the inmate at this point in the execution process." (OAL Decision of Disapproval at 18.) The Addendum to the Initial Statement of Reasons now states that "All inmates have a right to request medical care at any time." But it also states: "The three hour timeframe was selected because that is when the San Quentin Warden and the Team Administrator meet with the inmate, and because all in-person visiting ceases three hours prior to the scheduled execution, which may cause increased anxiety on the part of the inmate." (Addendum to ISR at 1.) First, the observation that inmates may request medical care at any time undercuts the selection of the three hour window. Second, the rationale that the three-hour timeframe was selected "because that is when the San Quentin Warden and the Team Administrator meet with the inmate" merely begs the question of why the meeting occurs at the three hour marker, rather than at another juncture. Third, there are many earlier steps in the execution process that would cause an inmate anxiety.

The Department's explanation still does not demonstrate by substantial evidence the need for the regulation's requirement to offer a sedative at this point, rather than any other point, in the execution process, and therefore, does not satisfy the necessity standard. It should be amended to remedy this defect.

16. Section 3349.6(i)(3) through 3349.6(i)(3)(E). Necessity.

The proposed regulation provides for a 7.5 gram dose. OAL found that CDCR's explanation for choosing a 7.5 dosage was not supported by substantial evidence, and thus failed to satisfy the necessity standard. (OAL Decision of Disapproval at 19.) CDCR has now provided an Addendum to the ISR, but the Addendum still fails to satisfy the necessity standard. CDCR now makes conflicting statements about whether a 5 gram dose is lethal. And it simply repeats the explanation previously provided, and previously found insufficient by OAL, for selecting a dose that exceeds 5 grams. In short, CDCR's selection of a 7.5 gram dose is not based on substantial evidence and instead entirely arbitrary.

CDCR's ISR states: "The Morales Plaintiffs' medical expert has agreed that 5 grams of thiopental is a lethal dose….While CDCR recognizes that 5 grams has been deemed lethal, CDCR chose to increase the dosage to 7.5 grams to take into account Lethal Injection Chemical tolerance, size or weight of the inmate." (ISR at 37.)

OAL found: "The explanation provided in the ISR and the identified documents relied upon lend support to the Department's determination that 5 grams of the named barbiturates is a lethal dose. However, the Department's explanation for choosing to increase the dosage amount to 7.5 grams, which is 2.5 grams greater than the stated lethal dosage, is not supported by substantial evidence. While the ISR states that 'CDCR chose to increase the dosage to 7.5 grams to take into account Lethal Injection Chemical tolerance, size or weight of the inmate' there is no explanation in the record to demonstrate that a 2.5 gram increase is necessary to address these potential variables. For example, what evidence is the Department relying on in determining that, for each of the four listed barbiturates, successful administration of 5 grams may be insufficient to result in a lethal dose. Similarly, assuming there is a need to increase the amount of Lethal Injection Chemical to account for these variables, what is the basis for increasing the dosage for each of the four listed barbiturates by 2.5 grams?" (OAL Decision of Disapproval at 19.)

The Addendum now states: "Although 5 g of Thiopental has been recognized as lethal, there is documentation showing that some inmates have continued to breathe after 5 g of Thiopental was injected (Rulemaking File documents relied upon: Vol. VI, Document 7 (p.4)). Therefore, in addition to the four 1.5 g doses totaling 6 g, CDCR has elected to administer an additional 1.5 g dose, for a total of 7.5 g, to take into account the inmates' Lethal Injection Chemical tolerance, age, size or weight, to ensure a result of death." (Addendum at 2.)

First, the Addendum now demonstrates why there is no substantial evidence to conclude that a 5 gram dose is lethal. As the ACLU previously explained in its July 8, 2016 Substantive Comments, the Plaintiffs' medical expert in the *Morales* litigation was addressing the question of whether sodium thiopental, as part of a 3-drug protocol, would produce *unconsciousness*, not the question of whether the drug, if administered as part of a 1-drug protocol, would produce *death*. (ACLU Substantive Comments [Comment Number 30406] at 33-34.) In any event, CDCR's ISR is now rife with contradictory statements about whether a 5 gram dose is lethal. The ISR, in sections unaffected by the Addendum to the ISR, contains CDCR's repeated assertion that a 5 gram dose is lethal. (*See, e.g.*, ISR at 7 ["it has been determined that a 5-gram dose is lethal"].) But the Addendum now contradicts that assertion: "there is documentation showing that some inmates have continued to breathe after 5 g of Thiopental was injected." (Addendum to ISR at 2.)

Second, the Addendum still fails to address OAL's concern that CDCR has not demonstrated by substantial evidence that a 5 gram dose is lethal *for each of the four drugs*. The ISR and Addendum to ISR discuss only evidence related to thiopental, but do not cite evidence related to the other three drugs. The evidence in the Record shows that the 3 other drugs are not pharmacologically equivalent and interchangeable. (*See* Comments of Craig W. Stevens, Professor of Pharmacology [Comment Number 30390] at 7.)

Third, the Addendum still fails to address OAL's concern that CDCR has not demonstrated by substantial evidence that *7.5 grams* is lethal for each of the four drugs. As discussed above, the Addendum now calls into question whether 5 grams is indeed lethal. And CDCR has still failed to cite any evidence to demonstrate that 2.5 grams beyond a potentially non-lethal 5 gram dose would be lethal. CDCR merely states that it "has elected" to administer this amount. (Addendum to ISR at 2.) And CDCR simply asserts, as it did in the initial ISR, that the additional amount above 5 grams was selected to account for differences in inmates' "tolerance, age, size or weight." (Addendum to ISR at 2.) But it still offers no evidence to support the conclusion that this amount suffices to address any such differences. As Professor Stevens explained, "increasing the dose of a drug does not always mean that the drug becomes more effective…. [I]n cases where drug tolerance is studied, increases much greater than 50% are need to bring about the effect seen in a non-tolerant patient." (Comments of Craig W. Stevens [Comment Number 30390] at 19.) Evidence to support the selection of 2.5 grams above the 5 grams is all the more important in light of CDCR's statement that a 5 gram dose may not be lethal.

CDCR's inability to establish a basis for its proposed 7.5 gram dose underscores the concerns previously articulated by the ACLU about CDCR's selection of these particular drugs for the protocol. (*See* ACLU Substantive Comments [Comment Number 30406] at 28-31 [use of amobarbital and secobarbital constitutes illegal biomedical research; manufacturer of pentobarbital has stated that it is not safe to use drug in lethal injection protocols; none of the four drugs is available from an FDA-approved manufacturer].) The very large dose also underscores the ACLU's previously articulated concerns about the extremely lengthy process entailed by CDCR's proposed protocol. (*See id.* at 23-25 [CDCR's own documents indicate that the infusion time for each syringe of pentobarbital would be 30 minutes, resulting in a minimum of 150 minutes for administration of each dose (5 syringes x 30 minutes)].)

The Department's explanation does not demonstrate by substantial evidence the need for the regulation's designation of a 7.5 gram dose, and therefore, does not satisfy the necessity standard. It should be amended to remedy this defect.

17. Section 3349.6(i)(3) through 3349.6(i)(3)(E). Clarity, necessity, and consistency.

The proposed regulation calls for the 7.5 gram dose to be administered in 5 60 cc syringes. OAL found that "[t]he record does not explain why or how the Department determined that five 60 cc syringes are necessary for administration of 7.5 grams of each of the four barbiturates identified as a Lethal Injection Chemical if selected for use in an execution." (OAL Decision of Disapproval at 20.) CDCR's Addendum to the ISR introduces additional issues of clarity, necessity, and consistency, and does not address OAL's previously stated concerns regarding necessity.

Issue 17.1. Clarity regarding preparation of syringes. The text of the regulation specifies that the 7.5 gram dose is to be administered in 5 60 cc syringes each containing 1.5 grams of the drug. The Addendum to the ISR now states: "CDCR will receive the designated

Lethal Injection Chemical in vials containing 500 mg of powder, which requires 20 cc of saline solution to reconstitute the designated Lethal Injection Chemical to the standard clinical solution of 2.5%. A 1.5 g bolus dose requires three 500 mg vials of powder mixed with 20 cc of saline solution each, totaling 60 cc of the designated Lethal Injection Chemical. The 60 cc syringe was chosen because it will hold the 1.5 g bolus dose." (Addendum to ISR at 2.) The ISR thus provides significantly more specificity about the manner in which the 5 syringes are to be prepared than is set forth in the regulatory text. In particular, it specifies that (1) the drug is to be obtained in *powder* form (rather than, for example, in premixed solution); (2) the drug is to be obtained in *500 mg vials* (rather than vials containing a different quantity of drug); (3) the drug is to be mixed with *saline* solution (rather than, for example) sterile water; and (4) the drug is to be diluted to *a concentration of 2.5%* (rather than a different concentration). This significant expansion of the regulation's requirements in the Addendum to the ISR creates a conflict between the language of the regulation and the Department's description of the effect of the regulation and thus raises a clarity issue.

Issue 17.2. Necessity regarding 5 syringes. The Addendum to the ISR still fails to explain why or how the Department determined that 5 syringes was necessary for administration of the 7.5 gram dose. To the extent the Department will be acquiring the drug in vials containing 500 mg (*i.e.*, 0.5 grams), it states that it intends to combine 3 vials into each of the 5 syringes. But it could also put 1 vial of powder in each syringe, and thus administer the dose in 15 syringes. It has simply offered no explanation of why it selected 5 syringes rather than a different number of syringes. The Department's explanation does not demonstrate by substantial evidence the need for the requirement to administer the dose in 5 syringes, and therefore, does not satisfy the necessity standard.

Issue 17.3. Necessity regarding 60 cc syringes. The Addendum to the ISR fails to explain why or how the Department determined that it should use 60 cc syringes for administration of the 7.5 gram dose. Syringes are commercially available in a wide range of sizes, ranging from 1 cc to 200 cc. (*See* Exhibit 2, Harvard Apparatus, "Syringe Selection Guide," *available at* http://www.harvardapparatus.com/media/harvard/pdf/Syringe%20Selection%20Guide.pdf.)[2] The Department states that it intends to dissolve each 500 mg vial in 20 cc of solution. Even assuming 500 mg of the drug could actually dissolve in 20 cc of solution (*but see* Issue 17.14 below), it could instead administer the 7.5 gram dose in 3 100 cc syringes rather than 5 60 cc syringes. The Department's explanation does not demonstrate by substantial evidence the need for the requirement to administer the dose in 60 cc syringes, and therefore, does not satisfy the necessity standard.

Issue 17.4. Clarity regarding "powder." The use of the term "powder" is unclear and could mean a pharmaceutically manufactured powder or active pharmaceutical ingredient (API) powder. (*See* Comments of Craig W. Stevens, Submitted March 25, 2017, at 2.) Professor Stevens explains the significant difference between these two forms of "powder," and in

[2] Exhibit 2 identifies commercially available syringes by volume in ml units. 1 cc is equivalent to 1 ml. *See* http://www.convertunits.com/from/cc/to/ml.

particular the infeasibility of dissolving the drugs in the specified amount of liquid, if API powder (as opposed to pharmaceutically manufactured powder) were acquired. The ambiguity as to whether the Department is supposed to acquire API powder or pharmaceutically manufactured powder raises a clarity issue.

Issue 17.5. Necessity regarding acquisition of drug in powder form. The Department has failed to explain why or how it determined that the drug should be obtained in powder rather than another form such as a premixed solution. This is of particular concern because, for example, pentobarbital has unique properties that require a highly complex method of preparation to ensure that the drug "will stay in solution and not precipitate out." (Comments of Craig W. Stevens [Comment Number 30390] at 21.) The Department's explanation does not explain why the drug should be obtained in powder form. The Department has not demonstrated by substantial evidence the need for the requirement to acquire the drug in powder form, and therefore, does not satisfy the necessity standard.

Issue 17.6. Necessity regarding acquisition of drug in 500 mg vials. The Department has failed to explain why or how it determined that the drug should be obtained in 500 mg vials. CDCR has pointed to no evidence regarding the packaging in which the drugs are available. Is each of the drugs identified in the protocol *only* available in 500 mg vials? If they are packaged in containers with different quantities of the drug, why did CDCR elect to acquire them in 500 mg vials? Is each of the drugs identified in the protocol available in 500 mg vials at all? Indeed, the record indicates that only one of the four drugs (amobarbital) is available in 500 mg vials of powder. (*See* Comments of Craig W. Stevens, Submitted March 25, 2017, at 6.) Thus, the requirement that the drug be acquired in 500 mg vials means that CDCR can only use amobarbital and would be unable to use any of the three other drugs in the protocol. The 500 mg vial requirement in this regard restricts the Department's ability to use the full range of drugs indicated in the protocol. (*See* Section 3349.5(f)(1)(C) (authorizing Warden to select from four drugs).) The Department's explanation does not demonstrate by substantial evidence the need for the requirement to acquire the drug in 500 mg vials, and therefore, does not satisfy the necessity standard.

Issue 17.7. Consistency regarding acquisition of drug in 500 mg vials. Only one of the four drugs (amobarbital) is available in 500 mg vials of powder. (*See* Comments of Craig W. Stevens, Submitted March 25, 2017, at 6.) Thus, the requirement that the drug be acquired in 500 mg vials means that CDCR can *only* use amobarbital and would be unable to use any of the three other drugs in the protocol. The 500 mg vial requirement is therefore inconsistent with the provision in the regulations authorizing the Warden to select from any of four drugs. (*See* Section 3349.5(f)(1)(C) (authorizing Warden to select from four drugs).) This conflict creates a consistency issue.

Issue 17.8. Necessity regarding use of saline solution. The Department has failed to explain why or how it determined that the powder should be dissolved in saline solution. This is of particular concern because, for example, the manufacturer of amobarbital calls for the drug to be dissolved in sterile water instead. (*See* Exhibit 3, Valeant, Prescribing Information for Amytal Sodium at 3.) Saline has a different pH from sterile water and its use would make it

harder to dissolve the drug. (*See* Comments of Craig W. Stevens, Submitted March 25, 2017, at 6.) The Department's explanation does not demonstrate by substantial evidence the need for the requirement to dissolve the drug in saline and therefore does not satisfy the necessity standard.

Issue 17.9. Consistency regarding use of saline solution. The Department proposes to dilute the drug in saline solution. (Addendum to ISR at 2.) But the regulations elsewhere state: "The Lethal Injection Chemical shall be mixed according to the manufacturer's instructions." (Proposed Section 3349.7(c)(12).) The manufacturer's instructions for amobarbital call for the drug to be dissolved in sterile water, not saline solution. (Exhibit 3, Valeant, Prescribing Information for Amytal Sodium at 3.) Thus, CDCR has provided conflicting and inconsistent instructions on whether, at least in the case of amobarbital, the chemical should be diluted in saline solution or sterile water. This conflict raises a consistency issue.

Issue 17.10. Clarity regarding use of saline solution. The Department proposes to dilute the drug in saline solution. (Addendum to ISR at 2.) But the regulations elsewhere state: "The Lethal Injection Chemical shall be mixed according to the manufacturer's instructions." (Proposed Section 3349.7(c)(12).) The manufacturer's instructions for amobarbital call for the drug to be dissolved in sterile water, not saline solution. (Exhibit 3, Valeant, Prescribing Information for Amytal Sodium at 3.) Thus, the regulations are ambiguous as to whether the Lethal Injection Team is to dilute the chemical in saline solution or sterile water. This raises a clarity issue.

Issue 17.11. Necessity regarding 2.5% concentration. The Department has failed to explain why or how it determined that the chemical should be reconstituted in a solution of 2.5%. The Addendum to the ISR refers to "the standard clinical solution of 2.5%." (Addendum to ISR at 2.) But the Department cites no evidence to support the assertion that 2.5% is "the standard clinical solution." This is of particular concern because, for example, the manufacturer of amobarbital states: "*Ordinarily*, a 10% solution is used." (*See* Exhibit 3, Valeant, Prescribing Information for Amytal Sodium at 3 [emphasis added].) The Department's explanation does not demonstrate by substantial evidence the need for the requirement to reconstitute the drug in a solution of 2.5% and therefore does not satisfy the necessity standard.

Issue 17.12. Consistency regarding 2.5% concentration. The Department proposes to dilute the drug to "the standard clinical solution of 2.5%." (Addendum to ISR at 2.) But the regulations elsewhere state: "The Lethal Injection Chemical shall be mixed according to the manufacturer's instructions." (Proposed Section 3349.7(c)(12).) The manufacturer's instructions for amobarbital state: *"Ordinarily*, a 10% solution is used." (Exhibit 3, Valeant, Prescribing Information for Amytal Sodium at 3 [emphasis added].) Thus, CDCR has provided conflicting and inconsistent instructions on whether, at least in the case of amobarbital, the chemical should be diluted to a 2.5% solution or a 10% solution. This conflict raises a consistency issue.

Issue 17.13. Clarity regarding 2.5% concentration. The Department proposes to dilute the drug to "the standard clinical solution of 2.5%." (Addendum to ISR at 2.) But the regulations elsewhere state: "The Lethal Injection Chemical shall be mixed according to the

manufacturer's instructions." (Proposed Section 3349.7(c)(12).) The manufacturer's instructions for amobarbital state: *"Ordinarily*, a 10% solution is used." (Exhibit 3, Valeant, Prescribing Information for Amytal Sodium at 3 [emphasis added].) Thus, the regulations are ambiguous as to whether the Lethal Injection Team is to prepare the chemical at a concentration of 2.5% or 10%. This raises a clarity issue.

Issue 17.14. Necessity regarding administration of 7.5 gram dose in 300 cc of solution. CDCR's protocol contemplates dissolving 7.5 grams of the drug in 300 cc of solution (5 syringes x 60 cc = 300 cc of solution). CDCR's decision to dissolve 7.5 grams of the drug in 300 cc of solution is not supported by substantial evidence.

CDCR explains its choice to administer the drugs in 5 60 cc syringes with the following statement: "CDCR will receive the designated Lethal Injection Chemical in vials containing 500 mg of powder, which requires 20 cc of saline solution to reconstitute the designated Lethal Injection Chemical…" (Addendum to ISR at 2.) But as Professor Stevens explains, it is only possible to dissolve 500 mg in 20 cc of solution if the drug is pharmaceutically manufactured amobarbital. None of the other three drugs can be dissolved in a solution of 500 mg / 20 cc, nor can amobarbital API powder. (*See* Comments of Craig W. Stevens, Submitted March 25, 2017, at 7.) In fact, far more than 20 cc of solution is required to dissolve 500 mg of each of the drugs in API powder form. To dissolve 500 mg of amobarbital API powder, 829 cc (mL) is needed; this translates into 12,435 cc (mL) (or 12.435 liters) of solution for a 7.5 g dose or 207 60 cc syringes. To dissolve 500 mg of pentobarbital API powder, 736 cc of solution is needed, which translates into 11,040 cc (mL) (or 11.040 liters) of solution for a 7.5 g dose or 184 60 cc syringes. To dissolve 500 mg of secobarbital API powder, 909 cc of solution is needed, which translates into 13,635 cc (mL) or 13.635 liters) of solution for a 7.5 g dose or 227 60 cc syringes. To dissolve 500 mg of thiopental API powder, 5,208 cc (mL) of solution is needed, which translates into 78,120 cc (mL) or (78.120 liters) of solution for a 7.5 g dose or 1,302 60 cc syringes. (*See id.* at 3-5.)

Drug	**Volume needed to dissolve 500 mg**	**Volume needed to dissolve 7.5 g**	**Total # of 60 cc syringes needed**
CDCR protocol	20 cc*	300 cc*	5
Amobarbital API powder	829 cc	12,435 cc	207
Pentobarbital API powder	736 cc	11,040 cc	184
Secobarbital API powder	909 cc	13,635 cc	227
Thiopental API powder	5,208 cc	78,120 cc	1,302

*Volume contemplated by CDCR's regulation, irrespective of actual chemical properties of drug.

If 60 cc syringes are used, it would be necessary to use between 184 and 1,302 syringes – a far cry from the 5 syringes required in CDCR's protocol – to administer the 7.5 gram dose. Given the low solubility of each of the four drugs, the Department has not demonstrated by

substantial evidence the need for a regulation requiring that 7.5 g of the drug be dissolved in 300 cc of liquid or delivered in 5 60 cc syringes, and therefore, does not satisfy the necessity standard.

Issue 17.15. Necessity regarding uniform protocol for each of four drugs. The regulation's requirement to deliver the chemical in 5 60 cc syringes assumes the Lethal Injection Team can dilute 500 mg of powder in 20 cc of solution. But as Professor Stevens explains, it is only possible to do so if the drug is pharmaceutically manufactured amobarbital. None of the other three drugs can be dissolved in a solution of 500 mg / 20 cc, nor can amobarbital API powder. (*See* Comments of Craig W. Stevens, Submitted March 25, 2017, at 7.) Professor Stevens' comments and the chart above illustrate that each drug has very different solubility properties, requiring different amounts of solution in which to dissolve the same amount of drug. Given the widely varying solubility properties of each of the four drugs, the Department has does not demonstrated by substantial evidence the need for a uniform protocol under which each of the four drugs is administered in 5 60 cc syringes, and therefore, does not satisfy the necessity standard.

The regulation and Department's statement of reasons should be amended to address these defects.

18. Section 3349.6(k). Clarity.

The new language addresses the timing of when the Team Supervisor is to ensure that there is an open phone line. The phrase "Approximately one hour prior to the scheduled execution" was replaced with "Within one hour prior to the scheduled execution." But the new language raises the identical concerns as the "approximately" language the OAL previously disapproved: it "creates ambiguity as to when the events subsequently listed are required to be performed and can be reasonably and logically interpreted to have more than one meaning." (OAL Decision of Disapproval at 11.) Would the Team Supervisor be in compliance if he or she performed the specified act 55 minutes before the execution? 10 minutes beforehand? The ambiguity creates a clarity issue. The regulation should be amended to address this defect.

19. Section 3349.6(d)(7)(A). Necessity.

The text establishes a $50 limit for the inmate's last meal. In an effort to address OAL's concern that the ISR failed to establish a necessity for the $50 limit, the Addendum to the ISR adds a discussion of limits on the cost of last meals in other states and data from Opentable.com of average to moderate full service meal costs in Marin County. But the opentable.com data reflects the cost of average to moderate full service meal costs for *in-restaurant* dining in Marin County. It does not reflect additional delivery costs to San Quentin State Prison, where the inmate will have the last meal. The Department has not demonstrated by substantial evidence the need for the $50 limit, and therefore, does not satisfy the necessity standard. The Department's statement of reasons should be amended to address this defect.

20. Failure to follow APA procedures regarding response to comments.

OAL found that CDCR had failed to adequately summarize and respond to all comments, including comments 3134-3136, 30713(2), 30834(7), 30398(5), 30403(46), and 33802(4). (OAL Decision of Disapproval at 21-23.) OAL stated: "Upon resubmission, all comments must be adequately summarized and responded to." (*Id.* at 21.) CDCR has not summarized or responded to *any* of the comments identified by OAL in its Decision of Disapproval. Its February 28, 2017 Notice of Change to Text as Originally Proposed contains a description of changes in the text of the regulations (NCR 15-10 Renotice at 1-7); a description of the modifications to forms (*id.* at 7-8); a description of a document added to the rulemaking file (*id.* at 8); the text of the proposed regulations (Text of Regulations NCR 15-10 Renotice at 1-30); revised forms; and an Addendum to the Initial Statement of Reasons (Addendum to ISOR NCR 15-10 at 1-3). The document published on February 28, 2017 and made available to the public at http://www.cdcr.ca.gov/Regulations/Adult_Operations/docs/NCDR/2015NCR/15-10/NCR_15-10_Renotice_March_8-March_27.pdf does not contain any supplemental response to comments. CDCR has therefore failed to address the defects identified by OAL.

21. Failure to follow APA procedures regarding record.

OAL found that the rulemaking record was incomplete because CDCR failed to include copies of comments 23,200 through 23,260 and 30887 in the record. (OAL Decision of Disapproval at 24.) CDCR has not supplemented the record with these comments, which are still missing. CDCR has therefore failed to address the defect identified by OAL.

* * *

For the foregoing reasons, the proposed regulations are deeply flawed and CDCR has failed to remedy their defects. CDCR should decline to proceed with the proposed action. If it does not, OAL should disapprove these regulations.

Sincerely,

Linda Lye
Senior Staff Attorney

Enclosure (Exhibits 1 through 3)

ACLU OF NORTHERN CALIFORNIA
Abdi Soltani, Executive Director
39 Drumm Street
San Francisco, CA 94111
(415) 621-2493

ACLU OF SOUTHERN CALIFORNIA
Hector Villagra, Executive Director
1313 West Eighth Street
Los Angeles, CA 90017
(213) 977-9500

ACLU OF SAN DIEGO & IMPERIAL COUNTIES
Norma Chavez-Peterson, Executive Director
P.O. Box 87131
San Diego, CA 92138
(619) 232-2121

EXHIBIT 1

DEPARTMENT OF CORRECTIONS AND REHABILITATION
Office of Legal Affairs
P. O. Box 942883
Sacramento, CA 94283-0001
(916) 445-0495
(916) 327-8706 fax

December 4, 2015

Ana Zamora
American Civil Liberties Union
Of Northern California
39 Drumm Street
San Francisco, CA 94111

Sent via electronic mail only - llye@ACLUnc.org

Re: Public Records Act Request dated September 4, 2015

Dear Ms. Zamora:

This is in response to your request for records from the California Department of Corrections and Rehabilitation (CDCR) dated September 4, 2015 and received on September 8, 2015. CDCR has completed its review of documents.

We have identified approximately 57 pages that may be responsive to your request. The duplication fees for this request are a total of $9.80 (57 pages at .12 each ($6.84) plus postage of $2.96). The responsive documents will be mailed upon receipt of this payment. Please mail the payment to: CDCR, Office of Legal Affairs, Attention: Dennis M. Beaty, 1515 S Street, Room 314S, Sacramento, CA 95811.

The ACLU has a scanned copy of the complete rulemaking file for the proposed Lethal Injection regulation. Additional responsive documents not exempted or privileged may include documents contained in the rulemaking file of the proposed regulations. The documents relied upon are listed in attachments A (vol. I) – attachments G (vol. VII) with their citations. CDCR has identified the following documents that may be responsive to your request: Attachment A (vol. I) documents 1-4, 8-9, 30, 37-39, 45-46, 48; attachment B (vol. II) document 1; attachment D (vol. IV) documents 1-70, attachment F (vol. VI) documents 1-4, 6-7, 14, 39, 42; attachment G (vol. VII) documents 1-9.

A portion of the records that you requested are exempt from disclosure under the Public Records Act and will not be provided to you. The applicable exemptions, more fully discussed below, include: Government Code §§ 6254 (a), (b), (c), (f) and (k); Business & Professions Code §§ 6068 and 6202; Evidence Code §§ 952, et seq. and 1040, and Code of Civil Procedure § 2018.030, et seq.; and Federal Rule of Civil Procedure Rule 26(b)(4)(D).

Records that are drafts not kept in the ordinary course of business will not be disclosed pursuant to Government Code § 6254 (a). (September 4, 2015 PRA request numbers 1, 2, 3, 5, 6, 7, 8, 11, 12.)

Documents that are protected by the attorney-client privilege, attorney work product, or were specifically prepared for CDCR's use in pending litigation or official information will not be disclosed pursuant to Government Code §§ 6254 (b) and (k), Business & Professions Code §§ 6068 and 6202; Evidence Code § 952, et seq. and 1040, and the Code of Civil Procedure § 2018.030, et seq; Federal Rule of Civil Procedure Rule 26(b)(4)(D); *Sara Lee Cork v. Kraft Foods Inc.* 273 F.R.D. 416. (September 4, 2015 PRA request numbers 1, 2, 3, 5, 6, 7, 8, 11, 12.)

Disclosure of some documents could compromise the safety and security of the institutions, staff, offenders, and others. These records will not be disclosed pursuant to Government Code §§ 6254 (f) and (k), Evidence Code § 1040, as discussed in *Procunier v. Superior Court of Monterey County* (1973) 35 Cal.App.3d 211. (September 4, 2015 PRA request numbers 1, 2, 3, 4, 5, 6, 7, 8, 11)

Records that would impose an unwarranted invasion of personal privacy, personnel records, or records deemed "protected information" by the Protective Order issued on April 3, 2006 in *Morales v. Woodford, et al.,* U.S. District Court for the Northern District of California case numbers 06 219 and 06 926 (including those indicating names, ranks, job descriptions, and other identifying information of members of the execution team) will be withheld consistent with the Protective Order, pursuant to Government Code §§ 6254 (f) and (k), Evidence Code § 1040, as discussed in *Procunier v. Superior Court of Monterey County* (1973) 35 Cal.App.3d 211, Government Code §§ 6254 (c) and (k), Penal Code §§ 832.7 and 832.8. (September 4, 2015 PRA request numbers 3, 4, 7, 8, 11.)

CDCR has no responsive documents for September 4, 2015 PRA request numbers 9 and 10.

If you have any questions I can be reached at (916) 324-3224.

Sincerely,

Dennis M. Beaty
Assistant General Counsel
PRA Unit

6-8-2015
Present: John Curzon SA
[redacted] SA

Attachment #1

Lethal Injection Facility
Sanitation Inspection Checklist

Date
6-8-2015

overall cleanliness needs to be addressed

Search Area	Comments
Sallyport Corridor	Floor requires cleaning
Sallyport Storage Room	Floor requires cleaning
Staging Area	Floor requires cleaning
Secure Holding Cell Area	Floor requires cleaning
Officer Security Area	Floor requires cleaning
Prep Room	Floor requires cleaning
Break Room	Floor needs to be cleaned
Rest Rooms	Floor needs to be cleaned
Prep Storage Room	Dusty / floor
Infusion/Control Room	Floor requires cleaning / bypass cleaning
Execution Room	Dusty
Electrical Room	needs basic organization
Storage Room	Dusty / floors
Victim Family Viewing Room	Dusty
Press Viewing Room	Dusty
Inmate Family Viewing Room	Dusty
All Doors & Gates Functioning	Yes

cabinets need deep cleaning

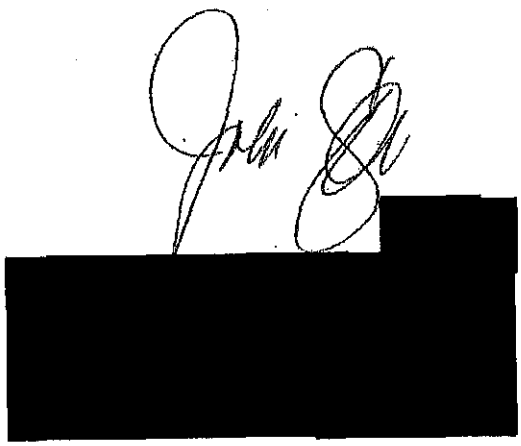
saline training

Lethal Injection Facility is in need of cleaning. Specifically, floors mopped, stripped and waxed. Facility has accumulated dust and dirt.

Lethal Injection Facility Safe Secure	yes
Light and Appliances Functioning	yes
Tool Inventory	ok
Refrigerator Temperature Indicate Temperature	Temperature_____ empty
Equipment Inventory Attach to Form	

_____ _____
Security Team Members Date

_____ _____
Execution Team Leader Date



6-8-2015 1115

6-8-15

EXHIBIT 2

Syringe Selection Guide

Common Syringe Data - Diameter and Plunger Surface Area

The following list is a guide to common syringes and their associated diameters and surface area. Syringe diameter data, in mm, is listed below for each syringe. All Harvard Apparatus microprocessor syringe pumps require the user to input syringe diameter information. The pump uses this diameter data to set flow rates. The PHD 22/2000 series of syringe pumps also has this information built into the pump memory in a handy Syringe Look Up Table. Surface area information was used to calculate PSI (pounds per square inch) data for the pressure table on page A93. Average pressures for any syringe pump and syringe combination can be calculated by dividing the average (nominal) syringe pump force by the syringe diameter (in square inches) to obtain PSI. Example, nominal pressure obtained using a 25 ml Hamilton Gastight® syringe on a PHD 22/2000 standard pressure syringe pump would be: 50 lbs / 0.644 in^2 = 77.6 PSI (5.35 bars).

Common Syringes and Their Diameters

Volume	Dia. (mm)	Area (in2)
BD Plastic		
1 ml	4.78	0.027815
3 ml	8.66	0.091297
5 ml	12.06	0.177059
10 ml	14.5	0.255952
20 ml	19.13	0.445505
30 ml	21.7	0.573247
50/60 ml	26.7	0.867851
BD Glass		
0.5 ml	4.64	0.026209
1 ml	4.64	0.026209
2.5 ml	8.66	0.091297
5 ml	11.86	0.171235
10 ml	14.34	0.250335
20 ml	19.13	0.445505
30 ml	22.7	0.627298
50 ml	28.6	0.995760
100 ml	34.9	1.482768
SGE Glass		
25 µl	0.73	0.000649
50 µl	1.03	0.001292
100 µl	1.46	0.002595
250 µl	2.3	0.006440
500 µl	3.26	0.012938
1 ml	4.61	0.025872
2.5 ml	7.28	0.064519
5 ml	10.3	0.129151
10 ml	14.57	0.258429
Harvard Stainless Steel		
8 ml	9.525	0.110447
20 ml	19.13	0.445505
50 ml	28.6	0.995760
100 ml	34.9	1.482768
200 ml	44.75	2.438382

Volume	Dia. (mm)	Area (in2)
Ranfac Glass		
2 ml	9.12	0.101254
5 ml	12.34	0.185376
10 ml	14.55	0.257720
20 ml	19.86	0.480154
30 ml	23.2	0.655237
50 ml	27.6	0.927343
Terumo Plastic		
3 ml	8.95	0.097514
5 ml	13	0.205735
10 ml	15.8	0.303904
20 ml	20.15	0.494279
30 ml	23.1	0.649601
60 ml	29.1	1.030881
Air-Tite All Plastic		
2.5 ml	9.6	0.112193
5 ml	12.45	0.188695
10 ml	15.9	0.307763
20 ml	20.05	0.489386
30 ml	22.5	0.616293
50 ml	29	1.023808
Popper & Sons Perfectum Glass		
0.5 ml	3.45	0.014490
1 ml	4.5	0.024652
2 ml	8.92	0.096862
3 ml	8.99	0.098388
5 ml	11.7	0.166646
10 ml	14.7	0.263061
20 ml	19.58	0.466711
30 ml	22.7	0.627298
50 ml	29	1.023808
100 ml	35.7	1.551525

Volume	Dia. (mm)	Area (in2)
Hamilton Gastight Glass		
0.5 µl	0.103	0.000013
1 µl	0.1457	0.000026
2 µl	0.206	0.000052
5 µl	0.3257	0.000129
10 µl	0.46	0.000258
25 µl	0.729	0.000647
50 µl	1.031	0.001294
100 µl	1.46	0.002595
250 µl	2.3	0.006440
500 µl	3.26	0.012938
1000 µl	4.61	0.025872
2.5 ml	7.28	0.064519
5 ml	10.3	0.129151
10 ml	14.57	0.258429
25 ml	23	0.643989
50 ml	32.6	1.293772
Unimetrics - 4000 and 5000 Glass		
10 µl	0.46	0.000258
25 µl	0.729	0.000647
50 µl	1.031	0.001294
100 µl	1.46	0.002595
250 µl	2.3	0.006440
500 µl	3.26	0.012938
1000 µl	4.61	0.025872
Kendall Monoject Plastic		
1 ml	4.65	0.026323
3 ml	8.94	0.097297
6 ml	12.7	0.196350
12 ml	15.9	0.307763
20 ml	20.4	0.506621
35 ml	23.8	0.689567
60 ml	26.6	0.861362
140 ml	38.4	1.795084

How to Select the Correct Syringe for Your Application

Syringe Type/Size	Swage Lock	Luer Lock	RN	Threaded 1/4• 28	Leur Slip Fit	Pressure Maximum p.s.i.	Compatibility with Substance in Syringe	Accuracy 1%	Accuracy 5%	Materials
Stainless Steel Syringes, see page A70										
8 ml	•					1,500	Maximum	•		316 / Chemraz
20 ml	•	•				750	Maximum	•		316 / Viton or Chemraz
50 ml	•	•				750	Maximum	•		316 / Viton or Chemraz
100 ml	•	•				750	Maximum	•		316 / Viton or Chemraz
200 ml	•	•				750	Maximum	•		316 / Viton or Chemraz
Glass GasTight Syringes, see pages A73 and A74										
1 to 100 µl		•	•	•	•	1,000	Maximum	•		Glass and Teflon
250 to 500 µl		•	•	•	•	500	Maximum	•		Glass and Teflon
1 to 10 ml		•	•	•		200	Maximum	•		Glass and Teflon
25 to 100 ml		•	•	•		100	Maximum	•		Glass and Teflon
Glass Multifit Syringes, see page A75										
2 to 50 ml		•				100	Maximum	•		Glass Only
Plastic Syringes, see pages A76 to A77										
1 ml		•			•	125	Minimum		•	Polypropylene and Natural Rubber
5 ml		•			•	125	Minimum		•	Polypropylene and Natural Rubber
10 ml		•			•	125	Minimum		•	Polypropylene and Natural Rubber
20 ml		•			•	125	Minimum		•	Polypropylene and Natural Rubber
30 ml		•			•	125	Minimum		•	Polypropylene and Natural Rubber
50/60 ml		•			•	125	Minimum		•	Polypropylene and Natural Rubber
140 ml		•			•	125	Minimum		•	Polypropylene and Natural Rubber

EXHIBIT 3

9476201 PC3328F

9476201 PC3328F

VIALS

AMYTAL® SODIUM

AMOBARBITAL SODIUM FOR INJECTION, USP

Rx only

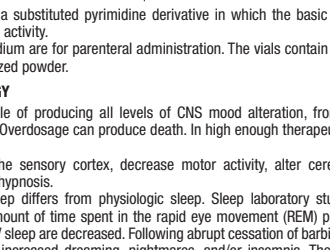
CAUTION: These products are to be used under the direction of a physician

The intravenous administration of Amytal® Sodium (Amobarbital Sodium for Injection, USP) carries with it the potential dangers inherent in the intravenous use of any potent hypnotic.

DESCRIPTION

The barbiturates are nonselective central nervous system (CNS) depressants that are primarily used as sedative hypnotics. In subhypnotic doses, they are also used as anticonvulsants. The barbiturates and their sodium salts are subject to control under the Federal Controlled Substances Act.

Amobarbital sodium is a white, friable, granular powder that is odorless, has a bitter taste, and is hygroscopic. It is very soluble in water, soluble in alcohol, and practically insoluble in ether and chloroform. Amobarbital sodium is sodium 5-ethyl-5-isopentylbarbiturate and has the empirical formula $C_{11}H_{17}N_2NaO_3$. Its molecular weight is 248.26. It has the following structural formula:



Amobarbital sodium is a substituted pyrimidine derivative in which the basic structure is barbituric acid, a substance that has no CNS activity.

Vials of amobarbital sodium are for parenteral administration. The vials contain 500 mg (2 mmol) amobarbital sodium as a sterile lyophilized powder.

CLINICAL PHARMACOLOGY

Barbiturates are capable of producing all levels of CNS mood alteration, from excitation to mild sedation, hypnosis, and deep coma. Overdosage can produce death. In high enough therapeutic doses, barbiturates induce anesthesia.

Barbiturates depress the sensory cortex, decrease motor activity, alter cerebellar function, and produce drowsiness, sedation, and hypnosis.

Barbiturate-induced sleep differs from physiologic sleep. Sleep laboratory studies have demonstrated that barbiturates reduce the amount of time spent in the rapid eye movement (REM) phase of sleep or the dreaming stage. Also, Stages III and IV sleep are decreased. Following abrupt cessation of barbiturates used regularly, patients may experience markedly increased dreaming, nightmares, and/or insomnia. Therefore, withdrawal of a single therapeutic dose over 5 or 6 days has been recommended to lessen the REM rebound and disturbed sleep that contribute to the drug withdrawal syndrome (for example, the dose should be decreased from 3 to 2 doses/day for 1 week).

In studies, secobarbital sodium and pentobarbital sodium have been found to lose most of their effectiveness for both inducing and maintaining sleep by the end of 2 weeks of continued drug administration, even with the use of multiple doses. As with secobarbital sodium and pentobarbital sodium, other barbiturates (including amobarbital) might be expected to lose their effectiveness for inducing and maintaining sleep after about 2 weeks. The short-, intermediate-, and to a lesser degree, long-acting barbiturates have been widely prescribed for treating insomnia. Although the clinical literature abounds with claims that the short-acting barbiturates are superior for producing sleep whereas the intermediate-acting compounds are more effective in maintaining sleep, controlled studies have failed to demonstrate these differential effects. Therefore, as sleep medications, the barbiturates are of limited value beyond short-term use.

Barbiturates have little analgesic action at subanesthetic doses. Rather, in subanesthetic doses, these drugs may increase the reaction to painful stimuli. All barbiturates exhibit anticonvulsant activity in anesthetic doses. However, of the drugs in this class, only phenobarbital, mephobarbital, and metharbital are effective as oral anticonvulsants in subhypnotic doses.

Barbiturates are respiratory depressants, and the degree of respiratory depression is dependent upon the dose. With hypnotic doses, respiratory depression produced by barbiturates is similar to that which occurs during physiologic sleep and is accompanied by a slight decrease in blood pressure and heart rate.

Studies in laboratory animals have shown that barbiturates cause reduction in the tone and contractility of the uterus, ureters, and urinary bladder. However, concentrations of the drugs required to produce this effect in humans are not reached with sedative-hypnotic doses.

Barbiturates do not impair normal hepatic function but have been shown to induce liver microsomal enzymes, thus increasing and/or altering the metabolism of barbiturates and other drugs (*see* Drug Interactions under Precautions).

Pharmacokinetics — Barbiturates are absorbed in varying degrees following oral or parenteral administration. The salts are more rapidly absorbed than are the acids. The rate of absorption is increased if the sodium salt is ingested as a dilute solution or taken on an empty stomach.

The onset of action for oral administration of barbiturates varies from 20 to 60 minutes. For intramuscular (IM) administration, the onset of action is slightly faster. Following intravenous (IV) administration, the onset of action ranges from almost immediately for pentobarbital sodium to 5 minutes for phenobarbital sodium. Maximal CNS depression may not occur until 15 minutes or more after IV administration for phenobarbital sodium. Duration of action, which is related to the rate at which the barbiturates are redistributed throughout the body, varies among persons and in the same person from time to time. Amobarbital sodium, an intermediate-acting barbiturate, is a CNS depressant. For the oral form, the onset of sedative and hypnotic action is 3/4 to 1 hour, with a duration of action ranging from 6 to 8 hours. These values should serve as a guide but not be used to predict exact duration of effect. No studies have demonstrated that the different routes of administration are equivalent with respect to bioavailability.

Barbiturates are weak acids that are absorbed and rapidly distributed to all tissues and fluids, with high concentrations in the brain, liver, and kidneys. Lipid solubility of the barbiturates is the dominant factor in their distribution within the body. The more lipid soluble the barbiturate, the more rapidly it penetrates all tissues of the body. Barbiturates are bound to plasma and tissue proteins to a varying degree, with the degree of binding increasing directly as a function of lipid solubility.

Phenobarbital has the lowest lipid solubility, lowest plasma binding, lowest brain protein binding, the longest delay in onset of activity, and the longest duration of action. At the opposite extreme is secobarbital, which has the highest lipid solubility, highest plasma protein binding, highest brain protein binding, the shortest delay in onset of activity, and the shortest duration of action. Amobarbital sodium is classified as an intermediate barbiturate. The plasma half-life for amobarbital sodium in adults ranges between 16 and 40 hours, with a mean of 25 hours.

Barbiturates are metabolized primarily by the hepatic microsomal enzyme system, and the metabolic products are excreted in the urine and, less commonly, in the feces. Only a negligible amount of amobarbital sodium is eliminated unchanged in the urine.

INDICATIONS AND USAGE

A. Sedative

B. Hypnotic, for the short-term treatment of insomnia, since it appears to lose its effectiveness for sleep induction and sleep maintenance after 2 weeks (*see* Clinical Pharmacology).

C. Preanesthetic

CONTRAINDICATIONS

Amobarbital sodium is contraindicated in patients who are hypersensitive to barbiturates, in patients with a history of manifest or latent porphyria, and in patients with marked impairment of liver function or respiratory disease in which dyspnea or obstruction is evident.

WARNINGS

1. Habit Forming — Amobarbital sodium may be habit forming. Tolerance, psychological and physical dependence may occur with continued use (*see* Drug Abuse and Dependence *and* Pharmacokinetics *under* Clinical Pharmacology). Patients who have psychological dependence on barbiturates may increase the dosage or decrease the dosage interval without consulting a physician and may subsequently develop a physical dependence on barbiturates. In order to minimize the possibility of overdosage or the development of dependence, the prescribing and dispensing of sedative-hypnotic barbiturates should be limited to the amount required for the interval until the next appointment. Abrupt cessation after prolonged use in a person who is dependent on the drug may result in withdrawal symptoms, including delirium, convulsions, and possibly death. Barbiturates should be withdrawn gradually from any patient known to be taking excessive doses over long periods of time (*see* Drug Abuse and Dependence).

2. Intravenous Administration — Too rapid administration may cause respiratory depression, apnea, laryngospasm, or vasodilation with fall in blood pressure.

3. Acute or Chronic Pain — Caution should be exercised when barbiturates are administered to patients with acute or chronic pain, because paradoxical excitement could be induced or important symptoms could be masked. However, the use of barbiturates as sedatives in the postoperative surgical period and as adjuncts to cancer chemotherapy is well established.

4. Usage in Pregnancy — Barbiturates can cause fetal damage when administered to a pregnant woman. Retrospective, case-controlled studies have suggested a connection between the maternal consumption of barbiturates and a higher than expected incidence of fetal abnormalities. Barbiturates readily cross the placental barrier and are distributed throughout fetal tissues; the highest concentrations are found in the placenta, fetal liver, and brain. Fetal blood levels approach maternal blood levels following parenteral administration.

Withdrawal symptoms occur in infants born to women who receive barbiturates throughout the last trimester of pregnancy (*see* Drug Abuse and Dependence).

If amobarbital sodium is used during pregnancy or if the patient becomes pregnant while taking this drug, the patient should be apprised of the potential hazard to the fetus.

5. Synergistic Effects — The concomitant use of alcohol or other CNS depressants may produce additive CNS-depressant effects.

PRECAUTIONS

General — Barbiturates may be habit forming. Tolerance and psychological and physical dependence may occur with continuing use *(see* Drug Abuse and Dependence).

Barbiturates should be administered with caution, if at all, to patients who are mentally depressed, have suicidal tendencies, or have a history of drug abuse. Particular caution is also indicated before administering barbiturates to patients who have abused other classes of drugs (*see* Warnings).

Elderly or debilitated patients may react to barbiturates with marked excitement, depression, or confusion. In some persons, especially children, barbiturates repeatedly produce excitement rather than depression.

In patients with hepatic damage, barbiturates should be administered with caution and initially in reduced doses. Barbiturates should not be administered to patients showing the premonitory signs of hepatic coma.

Parenteral solutions of barbiturates are highly alkaline. Therefore, extreme care should be taken to avoid perivascular extravasation or intra-arterial injection. Extravascular injection may cause local tissue damage with subsequent necrosis; consequences of intra-arterial injection may vary from transient pain to gangrene of the limb. Any complaint of pain in the limb warrants stopping the injection.

The systemic effects of exogenous and endogenous corticosteroids may be diminished by amobarbital sodium. Thus, this product should be administered with caution to patients with borderline hypoadrenal function, regardless of whether it is of pituitary or of primary adrenal origin.

Information for Patients — The following information should be given to patients receiving barbiturates.

1. The use of barbiturates carries with it an associated risk of psychological and/or physical dependence.

2. Barbiturates may impair the mental and/or physical abilities required for the performance of potentially hazardous tasks, such as driving a car or operating machinery. The patient should be cautioned accordingly.

3. Alcohol should not be consumed while taking barbiturates. The concurrent use of the barbiturates with other CNS depressants (eg, alcohol, narcotics, tranquilizers, and antihistamines) may result in additional CNS-depressant effects.

Laboratory Tests — Prolonged therapy with barbiturates should be accompanied by periodic evaluation of organ systems, including hematopoietic, renal, and hepatic systems (*see* General *under* Precautions *and* Adverse Reactions).

Drug Interactions — Most reports of clinically significant drug interactions occurring with the barbiturates have involved phenobarbital. However, the application of these data to other barbiturates appears valid and warrants serial blood level determinations of the relevant drugs when there are multiple therapies.

1. Anticoagulants — Phenobarbital lowers the plasma levels of dicumarol and causes a decrease in anticoagulant activity as measured by the prothrombin time. Barbiturates can induce hepatic microsomal enzymes, resulting in increased metabolism and decreased anticoagulant response of oral anticoagulants (eg, warfarin, acenocoumarol, dicumarol, and phenprocoumon). Patients stabilized on anticoagulant therapy may require dosage adjustments if barbiturates are added to or withdrawn from their dosage regimen.

2. Corticosteroids — Barbiturates appear to enhance the metabolism of exogenous corticosteroids, probably through the induction of hepatic microsomal enzymes. Patients stabilized on corticosteroid therapy may require dosage adjustments if barbiturates are added to or withdrawn from their dosage regimen.

3. Griseofulvin — Phenobarbital appears to interfere with the absorption of orally administered griseofulvin, thus decreasing its blood level. The effect of the resultant decreased blood levels of griseofulvin on therapeutic response has not been established. However, it would be preferable to avoid concomitant administration of these drugs.

4. Doxycycline — Phenobarbital has been shown to shorten the half-life of doxycycline for as long as 2 weeks after barbiturate therapy is discontinued.

This mechanism is probably through the induction of hepatic microsomal enzymes that metabolize the antibiotic. If amobarbital sodium and doxycycline are administered concurrently, the clinical response to doxycycline should be monitored closely.

5. Phenytoin, Sodium Valproate, Valproic Acid — The effect of barbiturates on the metabolism of phenytoin appears to be variable. Some investigators report an accelerating effect, whereas others report no effect. Because the effect of barbiturates on the metabolism of phenytoin is not predictable, phenytoin and barbiturate blood levels should be monitored more frequently if these drugs are given concurrently. Sodium valproate and valproic acid appear to increase the amobarbital sodium serum levels; therefore, amobarbital sodium blood levels should be closely monitored and appropriate dosage adjustments made as clinically indicated.

6. CNS Depressants — The concomitant use of other CNS depressants, including other sedatives or hypnotics, antihistamines, tranquilizers, or alcohol, may produce additive depressant effects.

7. Monoamine Oxidase Inhibitors (MAOIs) — MAOIs prolong the effects of barbiturates, probably because metabolism of the barbiturate is inhibited.

8. Estradiol, Estrone, Progesterone, and Other Steroidal Hormones — Pretreatment with or concurrent administration of phenobarbital may decrease the effect of estradiol by increasing its metabolism. There have been reports of patients treated with antiepileptic drugs (eg, phenobarbital) who become pregnant while taking oral contraceptives. An alternate contraceptive method might be suggested to women taking barbiturates.

Carcinogenesis — 1. Animal Data. Phenobarbital sodium is carcinogenic in mice and rats after lifetime administration. In mice, it produced benign and malignant liver cell tumors. In rats, benign liver cell tumors were observed very late in life.

2. *Human Data* — In a 29-year epidemiologic study of 9,136 patients who were treated on an anticonvulsant protocol that included phenobarbital, results indicated a higher than normal incidence of hepatic carcinoma. Previously, some of these patients had been treated with thorotrast, a drug that is known to produce hepatic carcinomas. Thus, this study did not provide sufficient evidence that phenobarbital sodium is carcinogenic in humans.

A retrospective study of 84 children with brain tumors matched to 73 normal controls and 78 cancer controls (malignant disease other than brain tumors) suggested an association between exposure to barbiturates prenatally and an increased incidence of brain tumors.

Usage in Pregnancy — 1. Teratogenic Effects. Pregnancy Category D — See Usage in Pregnancy under Warnings.

2. *Nonteratogenic Effects* — Reports of infants suffering from long-term barbiturate exposure in utero included the acute withdrawal syndrome of seizures and hyperirritability from birth to a delayed onset of up to 14 days (*see* Drug Abuse and Dependence).

Labor and Delivery — Hypnotic doses of barbiturates do not appear to impair uterine activity significantly during labor. Full anesthetic doses of barbiturates decrease the force and frequency of uterine contractions. Administration of sedative-hypnotic barbiturates to the mother during labor may result in respiratory depression in the newborn. Premature infants are particularly susceptible to the depressant effects of barbiturates. If barbiturates are used during labor and delivery, resuscitation equipment should be available.

Data are not available to evaluate the effect of barbiturates when forceps delivery or other intervention is necessary or to determine the effect of barbiturates on the later growth, development, and functional maturation of the child.

Nursing Mothers — Caution should be exercised when amobarbital sodium is administered to a nursing woman because small amounts of barbiturates are excreted in the milk.

Usage in Children — Safety and effectiveness have not been established in children below the age of 6 years.

ADVERSE REACTIONS

The following adverse reactions and their incidence were compiled from surveillance of thousands of hospitalized patients who received barbiturates. Because such patients may be less aware of certain of the milder adverse effects of barbiturates, the incidence of these reactions may be somewhat higher in fully ambulatory patients.

More than 1 in 100 Patients

The most common adverse reaction, estimated to occur at a rate of 1 to 3 patients per 100, is the following:

Nervous System: Somnolence

Less than 1 in 100 Patients

Adverse reactions estimated to occur at a rate of less than 1 in 100 patients are listed below, grouped by organ system and by decreasing order of occurrence:

Nervous System: Agitation, confusion, hyperkinesia, ataxia, CNS depression, nightmares, nervousness, psychiatric disturbance, hallucinations, insomnia, anxiety, dizziness, abnormality in thinking

Respiratory System: Hypoventilation, apnea, postoperative atelectasis

Cardiovascular System: Bradycardia, hypotension, syncope

Digestive System: Nausea, vomiting, constipation

Other Reported Reactions: Headache, injection site reactions, hypersensitivity reactions (angioedema, skin rashes, exfoliative dermatitis), fever, liver damage, megaloblastic anemia following chronic phenobarbital use

To report SUSPECTED ADVERSE REACTIONS, contact Valeant Pharmaceuticals North America LLC at 1-800-321-4576 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

DRUG ABUSE AND DEPENDENCE

Controlled Substance — Amobarbital sodium is a Schedule II drug.

Dependence — Barbiturates may be habit-forming. Tolerance, psychological dependence, and physical dependence may occur, especially following prolonged use of high doses of barbiturates. Daily administration in excess of 400 mg of pentobarbital or secobarbital for approximately 90 days is likely to produce some degree of physical dependence. A dosage of 600 to 800 mg for at least 35 days is sufficient to produce withdrawal seizures. The average daily dose for the barbiturate addict is usually about 1.5 g. As tolerance to barbiturates develops, the amount needed to maintain the same level of intoxication increases; tolerance to a fatal dosage, however, does not increase more than twofold. As this occurs, the margin between intoxicating dosage and fatal dosage becomes smaller.

Symptoms of acute intoxication with barbiturates include unsteady gait, slurred speech, and sustained nystagmus. Mental signs of chronic intoxication include confusion, poor judgment, irritability, insomnia, and somatic complaints.

Symptoms of barbiturate dependence are similar to those of chronic alcoholism. If an individual appears to be intoxicated with alcohol to a degree that is radically disproportionate to the amount of alcohol in his or her blood, the use of barbiturates should be suspected. The lethal dose of a barbiturate is far less if alcohol is also ingested.

The symptoms of barbiturate withdrawal can be severe and may cause death. Minor withdrawal symptoms may appear 8 to 12 hours after the last dose of a barbiturate. These symptoms usually appear in the following order: anxiety, muscle twitching, tremor of hands and fingers, progressive weakness, dizziness, distortion in visual perception, nausea, vomiting, insomnia, and orthostatic hypotension. Major withdrawal symptoms (convulsions and delirium) may occur within 16 hours and last up to 5 days after abrupt cessation of barbiturates. The intensity of withdrawal symptoms gradually declines over a period of approximately 15 days. Individuals susceptible to barbiturate abuse and dependence include alcoholics and opiate abusers, as well as other sedative-hypnotic and amphetamine abusers.

Drug dependence on barbiturates arises from repeated administration on a continuous basis, generally in amounts exceeding therapeutic dose levels. The characteristics of drug dependence on barbiturates include: (a) a strong desire or need to continue taking the drug; (b) a tendency to increase the dose; (c) a psychic dependence on the effects of the drug related to subjective and individual appreciation of those effects; and (d) a physical dependence on the effects of the drug, requiring its presence for maintenance of homeostasis and resulting in a definite, characteristic, and self-limited abstinence syndrome when the drug is withdrawn.

Treatment of barbiturate dependence consists of cautious and gradual withdrawal of the drug. Barbiturate-dependent patients can be withdrawn by using a number of different withdrawal regimens. In all cases, withdrawal requires an extended period of time. One method involves substituting a 30 mg dose of phenobarbital for each 100 to 200 mg dose of barbiturate that the patient has been taking. The total daily amount of phenobarbital is then administered in 3 or 4 divided doses, not to exceed 600 mg daily. If signs of withdrawal occur on the first day of treatment, a loading dose of 100 to 200 mg of phenobarbital may be administered IM in addition to the oral dose. After stabilization on phenobarbital, the total daily dose is decreased by 30 mg/day as long as withdrawal is proceeding smoothly. A modification of this regimen involves initiating treatment at the patient's regular dosage level and decreasing the daily dosage by 10% if tolerated by the patient.

Infants that are physically dependent on barbiturates may be given phenobarbital, 3 to 10 mg/kg/day. After withdrawal symptoms (hyperactivity, disturbed sleep, tremors, and hyperreflexia) are relieved, the dosage of phenobarbital should be gradually decreased and completely withdrawn over a 2-week period.

OVERDOSAGE

The toxic dose of barbiturates varies considerably. In general, an oral dose of 1 g of most barbiturates produces serious poisoning in an adult. Toxic effects and fatalities have occurred following overdoses of amobarbital sodium alone and in combination with other CNS depressants. Death commonly occurs after 2 to 10 g of ingested barbiturate. The sedated, therapeutic blood levels of amobarbital range between 2 to 10 mcg/mL; the usual lethal blood level ranges from 40 to 80 mcg/mL. Barbiturate intoxication may be confused with alcoholism, bromide intoxication, and various neurologic disorders. Potential tolerance must be considered when evaluating significance of dose and plasma concentration.

Signs and Symptoms — Symptoms of oral overdose may occur within 15 minutes beginning with CNS depression, absent or sluggish reflexes, underventilation, hypotension, and hypothermia and may progress to pulmonary edema and death. Hemorrhagic blisters may develop, especially at pressure points.

In extreme overdose, all electrical activity in the brain may cease, in which case a "flat" EEG normally equated with clinical death cannot be accepted. This effect is fully reversible unless hypoxic damage occurs. Consideration should be given to the possibility of barbiturate intoxication even in situations that appear to involve trauma.

Complications such as pneumonia, pulmonary edema, cardiac arrhythmias, congestive heart failure, and renal failure may occur. Uremia may increase CNS sensitivity to barbiturates if renal function is impaired. Differential diagnosis should include hypoglycemia, head trauma, cerebrovascular accidents, convulsive states, and diabetic coma.

Treatment — To obtain up-to-date information about the treatment of overdose, a good resource is your certified Regional Poison Control Center. Telephone numbers of certified poison control centers are listed in the *Physicians' Desk Reference* (*PDR*). In managing overdosage, consider the possibility of multiple drug overdoses, interaction among drugs, and unusual drug kinetics in your patient.

Protect the patient's airway and support ventilation and perfusion. Meticulously monitor and maintain, within acceptable limits, the patient's vital signs, blood gases, serum electrolytes, etc. Absorption of drugs from the gastrointestinal tract may be decreased by giving activated charcoal, which, in many cases, is more effective than emesis or lavage; consider charcoal instead of or in addition to gastric emptying. Repeated doses of charcoal over time may hasten elimination of some drugs that have been absorbed. Safeguard the patient's airway when employing gastric emptying or charcoal.

Diuresis and peritoneal dialysis are of little value; hemodialysis and hemoperfusion enhance drug clearance and should be considered in serious poisoning. If the patient has chronically abused sedatives, withdrawal reactions may be manifest following acute overdose.

PREPARATION OF SOLUTION

Solutions of amobarbital sodium should be made up aseptically with Sterile Water for Injection. The accompanying table will aid in preparing solutions of various concentrations. Ordinarily, a 10% solution is used. After Sterile Water for Injection is added, the vial should be rotated to facilitate solution of the powder. **Do not shake the vial.**

Several minutes may be required for the drug to dissolve completely, but under no circumstances should a solution be injected if it has not become absolutely clear within 5 minutes. Also, a solution that forms a precipitate after clearing should not be used. Amobarbital sodium hydrolyzes in solution or on exposure to air. Not more than 30 minutes should elapse from the time the vial is opened until its contents are injected. Prior to administration, parenteral drug products should be inspected visually for particulate matter and discoloration whenever solution containers permit.

Quantity of Sterile Water for Injection
Required to Dilute the Contents of a Given Vial of amobarbital sodium to Obtain the Percentages Listed.
Solutions Derived Will Be in Weight/Volume.

AMOBARBITAL SODIUM					
Content in Weight	1%	2.5%	5%	10%	20%
0.5 g	50 mL	20 mL	10 mL	5 mL	2.5 mL

DOSAGE AND ADMINISTRATION

The dose of amobarbital sodium must be individualized with full knowledge of its particular characteristics and recommended rate of administration. Factors of consideration are the patient's age, weight, and condition. The maximum single dose for an adult is 1 g.

Intramuscular Use — Intramuscular injection of the sodium salts of barbiturates should be made deeply into a large muscle. The average intramuscular dose ranges from 65 mg to 0.5 g. A volume of 5 mL (irrespective of concentration) should not be exceeded at any one site because of possible tissue irritation. Twenty percent solutions may be used so that a small volume can contain a large dose. After IM injection of a hypnotic dose, the patient's vital signs should be monitored. Superficial intramuscular or subcutaneous injections may be painful and may produce sterile abscesses or sloughs.

Intravenous Use — Intravenous injection is restricted to conditions in which other routes are not feasible, either because the patient is unconscious (as in cerebral hemorrhage, eclampsia, or status epilepticus), because the patient resists (as in delirium), or because prompt action is imperative. Slow IV injection is essential, and patients should be carefully observed during administration. This requires that blood pressure, respiration, and cardiac function be maintained, vital signs be recorded and equipment for resuscitation and artificial ventilation be available. The rate of IV injection for adults should not exceed 50 mg/min to prevent sleep or sudden respiratory depression. The final dosage is determined to a great extent by the patient's reaction to the slow administration of the drug.

Adults:

a. Sedative: 30 to 50 mg given 2 or 3 times daily.
b. Hypnotic: 65 to 200 mg at bedtime.

Special Patient Population — Dosage should be reduced in the elderly or debilitated because these patients may be more sensitive to barbiturates. Dosage should be reduced for patients with impaired renal function or hepatic disease. Ordinarily, an intravenous dose of 65 mg to 0.5 g may be given to a child 6 to 12 years of age.

HOW SUPPLIED

Amytal Sodium Vials 0.5 g (dry powder) are available as follows:
1 UNIT-PACK NDC 0187-4303-05
Store at 59° to 86°F (15° to 30°C).

Distributed by:
Valeant Pharmaceuticals North America LLC
Bridgewater, NJ 08807 USA

VALEANT

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